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28501	7590	12/18/2007	EXAMINER	
MICHAEL P. MORRIS			ANDERSON, JAMES D	
BOEHRINGER INGELHEIM CORPORATION				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/830,147	STEFANIC ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 July 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
 - 4a) Of the above claim(s) 18-30 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3 sheets</u> . | 6) <input type="checkbox"/> Other: _____. |

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CLAIMS 1-30 ARE PRESENTED FOR EXAMINATION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-18, compound T of claim 10 as the single antagonist recited in claim 1, part (i), and the compound of claim 16 as the single chemotherapeutic agent in claim 1, part (ii) in the reply filed on 7/30/2007 is acknowledged.

Claims 19-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie of chemotherapeutic agent, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 7/30/2007.

Priority

This application claims benefit to: EP 03 009 587, filed April 29, 2003; EP 04 000 508, filed January 13, 2004; EP 04 001 171, filed January 21, 2004; and U.S. Provisional Application 60/542,036, filed February 5, 2004.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Support for the instantly elected combination was found in EP 04 000 508, filed January 13, 2004 (see claims 1-18). EP 03 009 587 only provides support under 35 U.S.C. 112, 1st Paragraph for combinations comprising a steroid, but not for any and all chemotherapeutic

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agents as broadly claimed. Accordingly, the instant claims are afforded a priority date of January 13, 2004.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 2/3/2006. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Specification

The disclosure is objected to because of the following informalities:

(i) The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

(ii) A Brief Description of the Drawings is missing from the specification. See MPEP § 608.01(f). A reference to and brief description of the drawing(s) is required as set forth in 37 CFR 1.74.

Appropriate correction is required.

Claim Interpretation

Applicants are reminded that intended use of a pharmaceutical composition is not given patentable weight, unless the claimed use results in a physical difference between the claimed composition and any prior art compositions. In the instant case, claims 4-9 recite intended use

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limitations (e.g., "...wherein the combined preparation is for use in the treatment of oncological disorders"). As such, if a prior art composition (whether anticipatory or obvious) is capable of performing the recited use, such a composition meets the limitations of claims 4-9.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim 1 recites "...an antagonist of at least one receptor selected from VEGFR 1 to 3, PDGFR α and β , FGFR1, 2, and 3, EGFR, HER2, IGF1R, HGFR or c-Kit, which is further an antagonist of a src tyrosine kinase family member". The claimed Markush group selection is unclear as to what is being selected from. It is not apparent from the claims or specification whether the antagonist is selected from an antagonist of: (a) VEGFR 1, (b) VEGFR 2, (c) VEGFR 3, (d) PDGFR α , (e) PDGFR β , (f) FGFR1, (g) FGFR2, (h) FGFR3, (i) EGFR, (j) HER2, (k) IGF1R, (l) HGFR or (m) c-Kit; or, alternatively, if one must select from an antagonist of: (a) VEGFR 1, 2, and 3, (b) PDGFR α and β , (c) FGFR1, 2, and 3, (d) EGFR, (e) HER2, (f) IGF1R, (g) HGFR or (h) c-Kit. In other words, for those receptors with more than one sub-type, it is not apparent whether the antagonist must be an antagonist of all the recited sub-types; or if the antagonist must only antagonize one sub-type.

Claims 3 and 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The Markush groups recited in the claims are not in proper Markush format and thus it is not clear what is being selected from. For example, "...selected from CDK1, CDK2, CDK3, CDK4, CDK5, CDK6, CDK7, CDK8 and CDK9..." is unclear whether "CDK8 and CDK9" is one selection or if Applicants intend that either one or the other of CDK8 and CDK9 is selected.

Claims 3 and 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the limitation "an inhibitor of the paracrine IL-6 secretion" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claims 14 and 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, claims 14 and 15 recite parenthetical information (e.g. "irinotecan (camptosar)"). The information in parentheses is deemed indefinite because it can be interpreted as a claim limitation. For example it is not clear if the limitation "irinotecan (camptosar)" is intended to limit the selection to a specific formulation of irinotecan since Camptosar® is specific HCl injection formulation of irinotecan.

Claims 14 and 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that they fail to point out what is included or excluded by the claim language. These claims are omnibus type claims. Claims 14 and 15 contain numerous trademark/trade names (e.g., Iressa, Taxol, Camptosar, Revimid, etc). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. § 112, second paragraph. See *Ex parte Simpson*, 218

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USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade names are used to identify/describe chemotherapeutic agents to be used in pharmaceutical combinations and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 13-15 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain

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for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.I "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, the claims recite a genus of compounds that is defined only by the receptors of which they are antagonists (*e.g.*, claim 1). There is insufficient written description of the claimed antagonists, other than those compounds (A)-(U) as recited in claim 10 and pages 22-25 of the specification. The lack of written description of the instantly claimed genus is further compounded by the fact that the antagonists as instantly claimed must be antagonists, not of only one receptor, but of multiple receptors. Accordingly, other than compounds (A)-(U), Applicants have not demonstrated possession of the claimed antagonists of "at least one receptor selected from VEGFR 1 to 3, PDGFR α and β , FGFR1, 2, and 3, EGFR, HER2, IGF1R, HGFR or c-Kit, which is further an antagonist of a src tyrosine kinase family member" as recited in claim 1; and which is "...further an antagonist of at least one complex of a cyclin dependent

kinase with its specific cyclin or with a viral cyclin selected from CDK1, CDK2, CDK3, CDK4, CDK5, CDK6, CDK7, CDK8 and CDK9 with their specific cyclins A, B1, B2, C, D1, D2, D3, E, F, G1, G2, H, I and K, or an inhibitor of the paracrine IL-6 secretion” as recited in claim 3.

Aside from the very limited group of compounds recited in claim 10, Applicants provide no direction as to (a) what subset of compounds out of all possible compounds that exist in the art would have been reasonably expected to have activity in antagonizing the claimed receptor(s) and (b) which of those compounds actually *has* activity in antagonizing the claimed receptor(s) without having to execute hit or miss testing practices in order to make such a determination.

Although general techniques such as cellular assays may be known in the art, this fact fails to diminish the amount of experimentation that the skilled artisan would have to undertake to even identify, let alone determine the full scope of, the claimed antagonists of “at least one receptor selected from VEGFR 1 to 3, PDGFR α and β , FGFR1, 2, and 3, EGFR, HER2, IGF1R, HGFR or c-Kit, which is further an antagonist of a src tyrosine kinase family member” as recited in claim 1; and which is “...further an antagonist of at least one complex of a cyclin dependent kinase with its specific cyclin or with a viral cyclin selected from CDK1, CDK2, CDK3, CDK4, CDK5, CDK6, CDK7, CDK8 and CDK9 with their specific cyclins A, B1, B2, C, D1, D2, D3, E, F, G1, G2, H, I and K, or an inhibitor of the paracrine IL-6 secretion” as recited in claim 3, particularly in view of the fact that this genus as a whole is not one that is well-known or well-defined in the art such that the skilled artisan would readily envision those compounds that are within the scope of the claimed genus.

The need for testing amongst varying species of compounds to determine the full scope of the genus of antagonists instantly claimed demonstrates that Applicants were not in possession

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of the full scope of the genus now presently claimed. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention." Please see MPEP § 2163.

Despite the disclosure of the compounds defined in, e.g., claim 10, it remains that the specification provides non-limiting exemplification of a solely functional genus of agents that may be used within the context of the present invention. With the exception of compounds (A)-(U) as defined in the original disclosure and claims, Applicants are imposing the burden of extensive testing upon the skilled artisan to identify those other agents that may have any of the disclosed functions, but which Applicants have not identified and thus, were not in possession of, at the time of the present invention.

It has been held in patent law that a wish or plan for obtaining the invention as claimed does not provide adequate written description of a chemical invention. Rather, a precise definition, such as by structure, formula, chemical name or physical properties or a combination thereof, is required. Please reference, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004). In other words, though Applicants may have a plan for how to identify other agents that may be amenable for use in the present invention, it remains that at the time of the invention, Applicants had not identified such compounds, and, therefore, did not have written description of the full scope of the genus claimed.

Further, though Applicants have limited the claimed agents to those that perform a particular function, *e.g.*, those that antagonize certain receptors, it remains that Applicants have not appropriately defined the metes and bounds of the genus, even when limited by function (step-plus-function form). As taught in the MPEP at § 2163, step-plus-function claims are not adequately described if "the written description adequately links or associates adequately described particular structure, material or acts to the function recited in a step-plus-function claim limitation," or if "it is clear based on the facts of the application that one skilled in the art would have known what structure, material, or acts perform the function recited in a step-plus-function limitation." The instant application fails to meet these criteria. The present specification provides no disclosure beyond the generic disclosure of the required function that would correlate a common structural element or material to performance of the claimed function and that would be readily identifiable to one of skill in the art.

The same reasoning applies equally to the determination of the claimed polymorphs and metabolites of the claimed antagonists. The fact that one of ordinary skill in the art at the time of the invention would not only need to identify those compounds that are capable of functioning as antagonists of claimed receptors, but also that they would need to identify, synthesize, and test polymorphs and metabolites of such compounds in numerous disparate types of test cells to determine their activity in antagonizing the claimed receptors is clear and unequivocal evidence that Applicants were not in possession of the instantly claimed polymorphs and metabolites.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 01/27081 A1 (Published April 19, 2001) and WO 02/50043 A1 (Published June 27, 2002).

The instant claims recite pharmaceutical combinations comprising: (i) an antagonist of at least one receptor selected from VEGFR 1 to 3, PDGFR α and β , FGFR1, 2, and 3, EGFR, HER2, IGF1R, HGFR or c-Kit, which is further an antagonist of a src tyrosine kinase family member, or a polymorph, metabolite or pharmaceutically acceptable salt thereof; and (ii) at least a further chemotherapeutic or naturally occurring, semi-synthetic or synthetic therapeutic agent. The elected specie of (i) is (Z)-3-(1-(4-(N-((4-methyl-piperazin-1-yl)-methylcarbonyl)-N-methyl-amino)-phenylamino)-1-phenyl-methylene)-6-methoxycarbonyl-2-indolinone and the

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elected specie of (ii) is 4-[(3-chloro-4-fluorophenyl)amino]-6-{[4-(N,N-dimethylamino)-1-oxo-2-buten-1-yl]amino}-7-((S)-tetrahydrofuran-3-yloxy)-quinazoline.

WO 01/27081 teaches 6-substituted indolines of formula (I), in particular physiologically acceptable salts of said compounds, having activity in inhibiting different receptor-tyrosine kinases and cyclin/CDK complexes in addition to inhibiting the proliferation of endothelial cells and different tumor cells (Abstract). The invention also relates to medicaments containing said compounds (*id.*). The instantly elected (Z)-3-(1-(4-(N-((4-methyl-piperazin-1-yl)-methylcarbonyl)-N-methyl-amino)-phenylamino)-1-phenyl-methylene)-6-methoxycarbonyl-2-indolinone is taught at page 223 (compound 473). With respect to the limitations of claims 2-3, because the Office does not have experimental facilities, in the absence of a showing to the contrary, the properties of the claimed antagonists as recited in claims 2-3 are taken to be necessarily present in the compounds taught in WO '081 because such compounds include the instantly elected specie. Alternatively, if Applicants argue that compound 473 in WO '081 does not have these properties, claims 2-3 will be withdrawn in the next Office Action as being drawn to non-elected subject matter.

WO 02/50043 teaches quinazoline derivatives of general formula (I), especially physiologically acceptable salts with inorganic or organic acids (Abstract). Such compounds are disclosed to have an inhibitory effect upon signal transduction caused by tyrosine kinase and are taught to be useful in treating tumoral diseases (*id.*). The instantly elected 4-[(3-chloro-4-fluorophenyl)amino]-6-{[4-(N,N-dimethylamino)-1-oxo-2-buten-1-yl]amino}-7-((S)-tetrahydrofuran-3-yloxy)-quinazoline is exemplified as compound 18 on page 3. Pharmaceutical compositions comprising the disclosed compounds are taught at pages 36-41.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The instantly claimed combinations would have been *prima facie* obvious at the time the invention was made because the prior art teaches that both of the instantly elected compounds are disclosed by the prior art to be useful in treating tumors *via* inhibition of tyrosine kinases. As such, one skilled in the art would have been imbued with at least a reasonable expectation that a combination of these compounds would also be effective in treating tumors and thus would have been motivated to combine the individual compounds into a single pharmaceutical composition.

While the prior art references do not appear to explicitly suggest combining the disclosed compounds with other therapeutic agents (the Examiner is attempting to obtain an English translation of the documents in order to verify this teaching is not present), it is nonetheless *prima facie* obvious to combine two agents known to be useful for the same purpose into a single composition. One would have been motivated to do so because each of the therapeutics has been individually taught in the prior art to be useful in inhibiting tyrosine kinases and treating tumors. Moreover, the instant situation is amenable to the type of analysis set forth in *In re Kerkoven*, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior

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art. Applying the same logic to the instant claims, one of ordinary skill in the art would have been imbued with at least a reasonable expectation that a composition comprising a compound of WO '081 in combination with a compound of WO '043 would be at least as effective at inhibiting tyrosine kinases and tumor growth as the individual compounds.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James D. Anderson
Patent Examiner

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December 11, 2007

Ardin H Marschel 12/16/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER